

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:

George M. HALOW

Serial No.: 08/502,773

Filed : July 14, 1995

For : LAXATIVE/ANTI-DIARRHEAL COMPOSITION COMPRISING
POLYETHYLENE GLYCOL AND FIBER BULKING AGENT



Group Art Unit: 1205

Examiner: J. J. Reamer

#5
JRP
6/4/97

RESPONSE TO OFFICE ACTION

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In response to the Official Action dated February 25, 1997, applicant respectfully requests reconsideration of the refusal to allow claims 1-34 as presently on file.

The claimed inventive composition relates to the improvement on an ongoing basis of a patient's bowel function. Disclosed and claimed is a composition comprising polyethylene glycol and a fiber bulking agent, wherein the polyethylene glycol is present in a weight ratio of polyethylene glycol to fiber bulking agent of at least 1 to 2. The weight ratio and resultant composition is critical to the desired effect and intended use. Laxatives currently commercially available on the market fall within two categories, cathartics which rapidly improve bowl motility but which adversely affect bowl integrity, as by irritating sensitive bowel membranes and bulk laxatives, typically based on plant fibers or derivatives, which are much gentler and suitable for long term use, but which have a markedly slow onset of action and are not tolerated well by a significant number of patients.

The Examiner cited as a basis of the Office's refusal of claims 1-34 Leis, Jr. et al. in combination with Parker, Kimura et al. and Fordtram, as well as Powell et al. in combination with Parker, Kimura et al. and Fordtram. Powell et al., discussed in the background of the application, merely discloses a psyllium based bulk laxative which is combined with equal parts of a sugar wetting agent and water to provide a

hydrophilic aqueous composition which absorbs large amounts of water to provide bulk and thus normalize bowel function by improving stool formation. The patent focuses on the use of a polymer such as PEG, preferably in combination with polyvinyl pyrrolidone, as a wetting agent for psyllium powder in amounts of not more than 10%, preferably from about 2 to 5%, by weight of the wettable granules which are substantially psyllium. The process requires wet granulation of the psyllium powder coated with PEG and a volatile organic solvent such as alcohol, followed by dispersion of these granules in water. Nowhere in the document is there a discussion of the use of an improved composition for an ongoing regimen in an amount sufficient to improve bowel motility and/or stool formation. The Examiner states that the use of a higher ratio of PEG in the composition of Powell is considered to be obvious given the teachings of Kimura et al. and Fordtram that teach polyethylene glycol alone, as having laxative activity. This interpretation is a stretch and does not relate to the intended purpose of an ongoing regimen of treatment over a period of time rather than a cathartic type treatment. To change the ingredients or percentages in the Powell reference would render its intended use and result, inoperative and such there is no basis for taking a PEG "pure" teaching such as that of Kimura et al. or Fordtram and merely stating that one could take this material and increase the percentages set forth in Powell to teach a different composition, as set forth in the claimed invention.

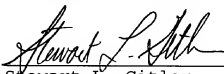
Regarding Leis, Jr. et al., this document nowhere teaches the use of polyethylene glycol in the percentages desired for the intended result of an ongoing treatment. This document merely teaches the use of a fiber bulking agent and an ionic wetting agent such dioctyl sodium sulfosuccinate in a composition to improve bowel function, as a laxative. To state that it would be obvious from the teaching of Parker to substitute polyethylene glycol for dioctyl sodium sulfosuccinate in a composition of Leis, Jr. et al. giving an equivalence teaching by a secondary reference is also a stretch. Nowhere is there a teaching of the regimen, use or intended results set forth by the claims of the

present invention. The percentages set forth in the claims are critical. If the PEG to fiber ratio is too low, rapid onset of activity of the products of the invention drops off and begins to approach the slow onset of a fiber based bulk laxative of the prior art. If the PEG to fiber ratio is too high, the volume of composition which must be ingested to obtain the benefits of the fiber content may be too high and the excess of PEG may result in undesirable side effects, such as those associated with PEG based bowel lavage compositions, such as set forth in Kimura et al. or Fordtram. The unique claimed composition is not habit forming and can be administered as needed or on a continual basis, without side effects or problems.

In summation, the claims as a presently set forth provide a unique composition containing polyethylene glycol and a fiber bulking agent wherein the PEG is present in a weight ratio of polyethylene glycol to fiber of from about 1 to 2 to no more than about 7 to 1. These percentages are critical and nowhere are they discussed or taught in the base references or the alleged equivalence teaching set forth by the secondary references. The unique regimen of taking the material on an ongoing basis without adverse side effects is nowhere taught or suggested by the documents set forth in the Official Action. The combining of short term and long term treatments to somehow assert equivalence would render these compositions inoperative.

If any questions remain please feel free to contact the undersigned.

Respectfully submitted,



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